GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:128
ANSWERED ON:22.11.2006
CLINICAL RESEARCH OUTSOURCING
Ponnuswamy Shri Mohan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has permitted Foreign Drug Patenting companies to do Clinical Research Outsourcing in India;

(b) if so, the details thereof;

(c) whether US based Quintiles Corporation conducted more than 100 clinical studies involving over 700 sites and nearly 15, 000 patients in India;

(d) if so, the details thereof including the conditions on which it was allowed to operate;

(e) the total number of such companies permitted to carry out clinical research in India; and

(f) the measures taken by the Government to safeguard people from ill effects of clinical studies?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)&(b) : As per the Drugs and Cosmetics Act & Rules thereunder, clinical trial applications can be made by foreign Clinical Research Organizations Clinical trials by these Organisations are permitted as part of global studies in which many countries participate.

(c) & (d): Quintiles Corporation, USA is a Clinical Research Organization engaged in clinical trials of drugs in the country. M/s. Quintiles Corporation has been allowed to conduct 90 clinical studies so far at approximately 600 sites involving nearly 5000 patients in India. The firm was permitted to conduct studies in India in accordance with the Drugs & Cosmetics Rules, Good Clinical Practice Guidelines and Indian Council of Medical Research ethical guidelines.

(e) & (f) : There are about 15 Clinical Research Organization which are presently engaged in clinical trials in India. The Clinical Trials are required to be conducted as per norms prescribed under the Drugs and Cosmetics Rules and Good Clinical Practice guidelines which prescribe the measures to be taken during the conduct of the trial viz. clearance from ethics committee, proper informed consent from patients as well as role of investigator, sponsor and the clinical research organization. Ethics committees are responsible for safeguarding the rights, safety and well being of the study subjects.